Application No.	Drug	Applicant
ANDA 76–978	Ondansetron HCl and Dextrose Injection	Do.
ANDA 77–362	Amlodipine Besylate Tablets	King and Spalding, U.S. Agent for Genpharm Inc., 1700 Pennsylvania Ave., NW., Washington, DC 20006–4706
ANDA 77–925	Meloxicam Tablets, 7.5 mg and 15 mg	Roxane Laboratories, Inc., 1809 Wilson Rd., Columbus, OH 43228
ANDA 85–153	Alkergot (ergoloid mesylates) Sublingual Tablets, 0.5 mg	Sandoz, Inc., 227–15 North Conduit Ave., Laurelton, NY 11413
ANDA 85–916	Diethylpropion HCl Tablets, 25 mg	Do.
ANDA 86–172	Meclizine HCl Tablets, 12.5 mg	Do.
ANDA 86–174	Meclizine HCl Tablets, 25 mg	Do.
ANDA 86–184	Sulfasalazine Tablets, 500 mg	Do.
ANDA 87–417	Alkergot (ergoloid mesylates) Sublingual Tablets, 1 mg	Do.
ANDA 89–565	Vinblastine Sulfate Injection, 10 mg/vial	Hospira, Inc.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner of Food and Drugs, approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective March 13, 2009.

Dated: January 12, 2009.

Douglas C. Throckmorton,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. E9–2901 Filed 2–10–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA2008E0091; Docket No. FDA2008E0099; Docket No. FDA2008E0204]

Determination of Regulatory Review Period for Purposes of Patent Extension; MACROPLASTIQUE IMPLANTS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for MACROPLASTIQUE IMPLANTS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of patents which claim that medical device.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device MACROPLASTIQUE IMPLANTS. MACROPLASTIQUE IMPLANTS are indicated for transurethral injection in the treatment of adult women diagnosed with stress urinary incontinence (SUI) primarily due to intrinsic sphincter deficiency (ISD). Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for MACROPLASTIQUE IMPLANTS (U.S. Patent Nos. 5,258,028;. 5,336,263; and 5,571,182) from Uroplasty, Inc., and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibilities for patent term restoration. In a letter dated May 6, 2008, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of MACROPLASTIQUE IMPLANTS represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for MACROPLASTIQUE IMPLANTS is 2,651 days. Of this time, 1,973 days occurred during the testing phase of the

regulatory review period, while 678 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) involving this device became effective*: July 30, 1999. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the act for human tests to begin became effective on June 30, 1999. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on July 30, 1999, which represents the IDE effective date.

2. *The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e)*: December 22, 2004. The applicant claims December 21, 2004, as the date the premarket approval application (PMA) for MACROPLASTIQUE IMPLANTS (PMA P040050) was initially submitted. However, FDA records indicate that PMA P040050 was submitted on December 22, 2004.

3. *The date the application was approved*: October 30, 2006. FDA has verified the applicant's claim that PMA P040050 was approved on October 30, 2006.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,640 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by April 13, 2009. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 10, 2009. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: January 17, 2009.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E9–2903 Filed 2–10–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–D–0043] (formerly Docket No. 2004D–0510)

Guidance for Industry: Referral Program From the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Fish and Fishery Products for Export to the European Union and the European Free Trade Association; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance document entitled "Guidance for Industry: Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Fish and Fishery Products for Export to the European Union and the European Free Trade Association." The revised guidance only changes the date on which FDA intends to stop issuing export certificates for fish or fishery products that are to be shipped to the European Union (EU) and the European Free Trade Association (EFTA). The date FDA now intends to stop issuing EU Export Certificates is June 17, 2009.

DATES: Submit written or electronic comments on the guidance at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Food Safety (HFS–300), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments concerning the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the guidance to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: William Jones, Center for Food Safety and Applied Nutrition (HFS–325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–2300.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 15, 2009 (74 FR 2600) (the January 15 notice), FDA announced the availability of a guidance entitled "Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Fish and Fishery Products for Export to the European Union and the European Free Trade Association." In the January 15 notice, FDA announced that it: (1) Intends to proceed with a Certification Referral Program to the National Oceanic and Atmospheric Administration Seafood Inspection Program (NOAA SIP), without a 24-month test period, (2) intends to expand the program to include all fish and fishery products for export to the EU and EFTA, and (3) intends to stop issuing EU Export Certificates effective February 17, 2009. The agency stated that it intends to adopt this approach because the industry's demand for EU Export Certificates continues to rise dramatically, and FDA can no longer justify the use of our limited food safety resources for issuance of EU Export Certificates. The implementation of this guidance should free up resources that the agency can allocate for higher priority public health activities that are intended to protect the U.S. consuming public, while still providing a mechanism for the industry to continue obtaining EU certification. Seafood processors and other entities involved in the exporting of seafood to the EU may obtain EU Export Certificates from the NOAA SIP.